This form is for use between National Competent Authorities (NCA) only

1.Report from **NCA** in:_____(country) 2.Ref.no.:_____(national seq. no.) 3.Sent by:_____(date) (sign)

4.Contact point:_____ 5. Contact person:_____

6.Tel:_____ 7.Fax:_____ 8.

DEVICE DATA:

9.Generic name / kind of device:

10.Nomenclature id.:_____(which nomenclature) 11.No.:_____(code)

12.Type / (make & model):

13.Software version:

14.Serial no.: 15.Lot/batch no.:

16.Manufacturer / authorized rep: 17.Country: _____ Tel: _____

18.CAB / NB:

19.Regulatory action taken? (what kind):

20.Device approval status:

For pt. 21-22-23 use additional pages if necessary.

21.**Reason for this report:**

22a.**Conclusions / suggested actions:**

b. NCA of _____ is willing to take the lead and coordinate the investigation

23.**Recommendations to receivers of this report:**

24a.This report has been sent to the **National Competent Authorities** in:

All EEA states AU CA CH JP NZ US

and _____ | _____ | _____ | _____ | _____

b. The manufacturer / authorized rep.:

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This document has been created by the members of the Global Harmonization Task Force - Study Group 2 on Medical Devices Vigilance/ Post Market Surveillance. The terms used in this document should be interpreted as defined by current regulatory requirements and/ or standards. The information and guidance herein represents a harmonized proposal, which may not reflect current regulatory requirements.

Instructions for filling in the Form on page 1: This form should be used by *National Competent Authorities (NCA)* only, when exchanging information about relevant measures and/ or recommendations relating to the prevention of adverse incidents concerning *medical devices*. It is not to be used for informing of single incidents, unless those incidents have a clear implication for public health. In such cases the implied recommendation is for other NCAs to be aware and take such local actions they find appropriate.

The Authority filling in and sending the form will be *responsible for the quality of the content* as well as the *appropriateness* of sending such a message. The content should normally be considered to be «commercial in confidence» and hence be handled accordingly. Before releasing any information, careful note should be taken of the *Guidelines on When and how to inform about adverse events nationally.*

If information will have to be conveyed to others, it is recommended that this is done in a discreet manner, not making more noise than strictly necessary. See the *Guidelines on When and how to inform about adverse incidents nationally.* This form is for NCAs and should not be passed directly on to patients, users, third person or the public.

Items 1 - 8 - concerning the Reporter: These items must clearly identify the Authority responsible for this Report, and making it possible for the receiver to come into contact for further information.

Items 9 - 17 - Device Data: To make certain the device in question is properly identified, these items must give as much accurate information as possible. If the device can be classified in a recognized nomenclature (e.g. GMDN, MHW, NKKN, UMDNS) this will be of value (no 10). 14 - 15 identifies devices *affected* by this report. Items 16 - 17 points to who is legally responsible for placing the device in question on the market in the area where the incidents occured (EEA, USA &c).

Item 18: Give name or code number of Conformity Assessment Body/ NB concerned.

Item 19: Any regulatory or legal action taken in advance of sending out this Report should be stated here. This could for instance refer to use of the Safegard Clause.

Item 20: Approval status of the device in the region where the report stems from, i.e. where the incidents occured. This could be, inter alia, CE-marking and Risk Class or FDA Approval number.

Item 21 - Reason for this report: Here a description of what has happened, as well as factual background information, should appear. Such information might lead to a better understanding by the recepient on how to make an appropriate follow-up. Similarly, who has done the investigation leading to this Report could be of importance for further follow-up. Sometimes an Authority (where incidents occured, manufacturer's premises, assessment body location) volunteers for a role as a coordinator of any further investigation (21b).

Item 22 - Conclusions or suggested actions: This will describe the outcome or the investigation. Normally at this stage the investigation will have reached some conclusions or be finalized. There can, however, be reasons for disseminating an alert at an earlier stage, even without conclusive evidence of a serious risk to patient safety.

Item 23 - Recommendations to receivers of this report: Here should appear what action the receiving Authority is recommended to do nationally upon being informed. If known, what countries the device has been sold in should be told here.

Item 24 - This report has been sent to the National Competent Authorities in: the following countries (ISO coded here). Normally it will be of help, or of support, to know who else has received this Report. The manufacturer, or his authorized representative, should always be provided with a copy. JWN12JUNE97